FEB 2 0 2004

510(K) SUMMARY

Subject 510(k) Number

K040199
page 1 of 1

Sponsor

Osseus, LLC

3131 Princeton Pike
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Lawrenceville, NJ 08648

Official Contact

Shawn T. Huxel, President/GM
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Lawrenceville, NJ 08648
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Proprietary Name

Osse-Lign

Common Name

Metallic Internal Fixation Device

Classification Name and Reference

888.3010 - Bone Fixation Cerclage

Regulatory Class

Class II

Device Product Code

(Panel 87) JDQ

Date Prepared

27 January, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Mr. Shawn T. Huxel
President/General Manager
Osseus, LLC
3131 Princeton Pike
Building 5, Suite 200
Lawrenceville, New Jersey 08648

Re: K040199
Trade/Device Name: 1.5 mm Osse-Lign Internal Fracture Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: January 27, 2004
Received: January 29, 2004

Dear Mr. Huxel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (K) NUMBER IF KNOWN: K040199

DEVICE NAME: 1.5 mm Osse-Lign Internal Fracture Fixation System

The Osse-Lign System is indicated for general orthopedic repairs. This includes such procedures as long bone fractures, bone grafting and reinforcement of bone. This system may also be used for supplementary fixation and reduction with approved bone plates, screws, pins, nails and bone grafting material.

Long Bone Fractures

- Femur fractures
- Tibia fractures
- Humerus fractures

Joint Fractures

- Ankle fractures
- Knee Fractures
- Hip Fractures
- Shoulder Fractures
- Elbow Fractures

Other bone fractures

- Olecranon
- Pelvis fractures
- Patella fractures
- Acetabular fractures
- Trocanteric reattachment
- Fixation of fractures in conjunction with I/M nailing and plating techniques
- Stabilization of cortical onlay strut graft
- Temporary reduction techniques for ORIF (Open Reduction Internal Fixation)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **or** **Over-the-Counter Use** _____

(Per 21 CFR 801.109) (Optional Format 1-2-1996)

for Mark N. Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K040199